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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,006	07/24/2001	Donald Shannon	VAS-4761CONDIV	5855

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Edwards Lifesciences LLC
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EXAMINER

ROSSI, JESSICA

ART UNIT	PAPER NUMBER
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1733

DATE MAILED: 03/05/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,006

Applicant(s)

SHANNON ET AL.

Examiner

Jessica L. Rossi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/30/03, Amendent C.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment dated 1/30/03. Claims 1-11 were canceled. Claims 23-32 were added.
2. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by the Admitted Prior Art, as set forth in the previous office action, has been withdrawn in light of Applicant's amendment.
3. The rejection of claims 1-4 and 7-8 under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in view of Hiroyoshi (of record) and House et al. (of record), as set forth in the previous office action, has been withdrawn for the reason stated above.
4. The rejection of claims 1 and 9 under non-statutory obviousness-type double patenting as being unpatentable over US 5,843,173, as set forth in the previous office action, has been withdrawn in light of Applicant's arguments.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 25-26 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, it recites the limitation "the sintered, longitudinally expanded tubular PTFE extrudate" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to make this claim dependent on claim 24.

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Regarding claim 26, it is unclear as to how this claim differs from claim 24, especially since claim 26 recites a method step that gets no weight in an article claim. Applicants are asked to clarify. It is suggested to delete this claim.

Regarding claims 30-31, it is unclear as to how these claims further limit claim 29, since they recite method steps that get no weight in an article claim. Applicants are asked to clarify. It is suggested to delete these claims and make claim 32 dependent on claim 29.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by the Admitted Prior Art in the specification of the present application.

*It is noted that Applicants invention is directed to enlarging the diameter of an expandable tape-reinforced graft without breaking or tearing the reinforcing tape. Applicants achieve this goal in two ways: by 1) wrapping an expanded PTFE tape around an expanded PTFE base graft and reducing the diameter of the assembly prior to enlarging it (p. 5, lines 9-12) or by 2) reducing the diameter of an expanded PTFE tape and wrapping the reduced tape around a small diameter expanded PTFE base graft prior to enlarging the assembly (p. 13, lines 13-51).

With respect to claim 23, it appears that Applicants teach it is known in the art to have a radially expandable tape-reinforced tubular vascular graft comprising a tubular PTFE base graft and a reinforcing tape wrapped around the base graft, wherein the graft is capable of undergoing radial enlargement to increase its diameter without breaking or tearing of the tape (p. 1, line 22 – p. 2, line 13). The examiner recognizes that the graft of the Admitted Prior Art is only capable of

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undergoing enlargement by an amount <5% before tearing of the tape begins (p. 2, lines 10-13);

however, minimal enlargement capabilities **do not mean** no enlargement capabilities.

Furthermore, the present claim does not exclude grafts that undergo enlargement of <5%, as evidenced by claims 25 and 28.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in view of House et al. (US 5026513; of record).

With respect to claims 24 and 26, the Admitted Prior Art teaches the base graft comprising a sintered, expanded PTFE tube (p. 1, line 22 – p. 2, line 5) but is silent as to the base graft being a longitudinally expanded extrudate.

It is known in the art to make articles, such as vascular grafts (column 4, lines 60-62), comprising expanded PTFE extrudate materials (tubes, films, sheets, etc.) where tearing of the materials during enlargement is overcome by reducing the size of the materials prior to enlargement, as taught by House (column 1, lines 62-68; column 2, lines 1-11 and 43-44 and 55-60; column 3, lines 25-27; column 4, lines 4-7). House teaches these materials being expanded either uniaxially, biaxially, or multiaxially (column 2, line 65 – column 3, line 2). For example, House teaches uniaxially expanding in the longitudinal direction (column 6, lines 52-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the base graft of the Admitted Prior Art be a longitudinally expanded

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extrudate because such is known in the art, as taught by House, where only the expected results of increasing the porosity of the base graft would have been achieved.

Regarding claims 25 and 28, the Admitted Prior art is silent as to the base graft being capable of radial enlargement by an amount $\geq 5\%$. House teaches reducing the size of the PTFE expanded materials in a direction parallel but opposite to the direction in which they were expanded; therefore, the materials can be reduced either uniaxially, biaxially, or multiaxially (column 3, lines 25-27), where the skilled artisan reading the reference as a whole would have readily appreciated that biaxially and multiaxially would have to include the radial direction when dealing with a tube. House teaches that this reduction in size of the expanded PTFE materials allows for enlargement of the same by an amount $>5.5\%$ without any breaking or tearing (column 1, lines 62-68; column 2, lines 40-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the expanded base graft and/or graft of the Admitted Prior Art be capable of being reduced in the radial direction prior to enlargement of the same so that the base graft and/or graft is capable of radial enlargement by at least 5% because such is known in the art, as taught by House, where this allows for enlargement of the base graft and/or graft by an amount $>5.5\%$ without any breaking or tearing.

Regarding claim 27, House teaches the materials being expanded by a ratio of more than 2:1 (column 6, lines 30-36).

With respect to claim 29, Applicants are directed to paragraph 8 above for a complete discussion of the Admitted Prior Art. The Admitted Prior Art teaches all the limitations except the base graft being radially reduced in size and the tape being reduced in size.

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As set forth above, it is known in the art to make articles, such as vascular grafts (column 4, lines 60-62), comprising expanded PTFE materials (tubes, films, sheets, etc.) where tearing of the materials during enlargement is overcome by reducing the size of the materials prior to enlargement, as taught by House (column 1, lines 62-68; column 2, lines 1-11 and 43-44 and 55-60; column 3, lines 25-27; column 4, lines 4-7).

House teaches these materials being expanded either uniaxially, biaxially, or multiaxially (column 2, line 65 – column 3, line 2), such as in the longitudinal direction (column 6, lines 52-53), and reducing the size of the expanded materials in a direction parallel but opposite to the direction in which they were expanded; therefore, the materials can be reduced in size either uniaxially, biaxially, or multiaxially (column 3, lines 25-27), where the skilled artisan reading the reference as a whole would have readily appreciated that biaxially and multiaxially would have to include the radial direction when dealing with a tube.

House teaches that this reduction in size of the expanded PTFE materials allows for enlargement of the same by an amount $>5.5\%$ without any breaking or tearing (column 1, lines 62-68; column 2, lines 40-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an expanded base graft that is radially reduced in size and an expanded tape that is reduced in size for the graft of the Admitted Prior Art because such is known in the art, as taught by House, where this allows for the graft to be enlarged by an amount $>5.5\%$ without tearing or breaking of the graft materials.

Regarding claims 30-31, it is noted that the claimed limitations are recited as method steps that do not get any weight in an article claim.

Regarding claim 32, Applicants are directed to the rejection of claim 29.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34-35, and 41 of U.S. Patent No. 5,928,279 (of record) in view of the Admitted Prior Art.

Although the US Patent claims are directed to a combination of articles (stent and graft), the present invention is not patentably distinct because the US Patent claims encompass the limitations of the present claims when taken with the Admitted Prior Art, as set forth above in paragraph 8.

13. Claims 24-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34-35, and 41 of U.S. Patent No. 5,928,279 in view of the Admitted Prior Art and House et al.

Although the US Patent claims are directed to a combination of articles (stent and graft), the present invention is not patentably distinct because the US Patent claims encompass the

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limitations of the present claims when taken with the Admitted Prior Art and House, as set forth above in paragraph 10.

Response to Arguments

14. Applicant's arguments filed 1/30/03 have been fully considered but they are not persuasive.

15. On page 4 of the arguments, Applicants argue that the Admitted Prior art fails to anticipate the present invention disclosed in present claim 23, because the Admitted Prior Art teaches minimal expansion without tearing of the tape.

The examiner invites Applicants to reread the rejection set forth in paragraph 8 above. Once again, minimal expansion without tearing is still expansion without tearing.

16. On page 5 of the arguments, Applicants argue that the double patenting rejection using the '279 Patent is improper because those claims are directed to a stent/graft combination as opposed to just a graft as claimed in the present invention.

The examiner points out that the fact that the claims of the '279 Patent include more than just a graft has no bearing on its applicability as a double patenting reference against the claims of the present invention.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **703-305-5419**. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael W. Ball can be reached on 703-308-2058. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jessica L. Rossi
Patent Examiner
Art Unit 1733



jl原因
February 28, 2003



Michael W. Ball
Supervisory Patent Examiner
Technology Center 1700